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YY

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1921-2023

Closed type copper-bearing contraceptive intrauterine devices

闭环式含铜宫内节育器

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents" Drafting. Please note that some content in this document may be subject to patents. Release of this document The Agency assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Technical Committee on Standardization of Family Planning Devices (SAC/TC169). This document was drafted by: Wuhan Weimin Medical Equipment Co., Ltd., Shanghai Medical Suture Needle Factory Co., Ltd., Shanghai Medical Equipment Co., Ltd. Inspection Institute, Yantai Family Planning Pharmaceutical Equipment Co., Ltd., Henan Yakang Pharmaceutical Co., Ltd., Jiangsu Medical Device Inspection Institute. The main drafters of this document. Sun Xinhan, Duan Zhuo, Yao Tianping, Tian Yunxia, Zhong Xiuyun, Zheng Dixin, Yin Fengxia, Qian Xinyi, Gu Xiaoyu, Wang Weiguang, Chen Zheng, Li Haiqi. Closed-loop copper intrauterine device

1 Scope

YY/T 1921 covers the closed-loop copper intrauterine device, the ring-form IUD whose frame has no free ends. It sets the requirements such a device has to meet and the test methods that verify them, covering the copper surface area and its release, the mechanical strength and elasticity of the loop, the dimensions, the removal thread, and the sterility and packaging of the product. Closed-loop designs were developed to reduce perforation and expulsion, and the closed geometry is exactly what has to be verified: a loop that opens or fractures inside the uterus becomes a surgical problem. Copper IUDs are the dominant reversible contraceptive in China and are manufactured there at scale. For a manufacturer, this is the document a Chinese registration is assessed against.

YY/T 0149 Test method for corrosion resistance of stainless steel medical instruments

YY/T 0334-2022 General requirements for silicone rubber surgical implants

YY/T 0640-2016 General requirements for passive surgical implants

YY/T 1404 Technical requirements and test methods for copper used in copper-containing intrauterine devices

YY/T 1471-2016 Technical requirements and test methods for indomethacin-containing silicone rubber for copper-containing intrauterine devices "Pharmacopoeia of the People's Republic of China" (2020 edition)

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 4240 stainless steel wire

GB/T 4340.1 Vickers hardness test of metallic materials Part

3 Terms and definitions

The following terms and definitions as defined in GB 11236-2021 apply to this document.

3.1 closed type Connected end to end, they form a closed structure similar to the shape of a uterine cavity.

3.2 corrosion resistance corrosion resistance The ability of metallic materials to resist the corrosive and damaging effects of the surrounding medium.

3.3 Deformation recovery ability visco-elastic property The IUD can roughly return to its original shape after deformation.